(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 May 2004 (06.05.2004)

PCT

(10) International Publication Number
WO 2004/037128 A1

(51) International Patent Classification[7]: A61F 2/24, 2/06

(21) International Application Number:
PCT/US2003/033521

(22) International Filing Date: 23 October 2003 (23.10.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/420,905 24 October 2002 (24.10.2002) US

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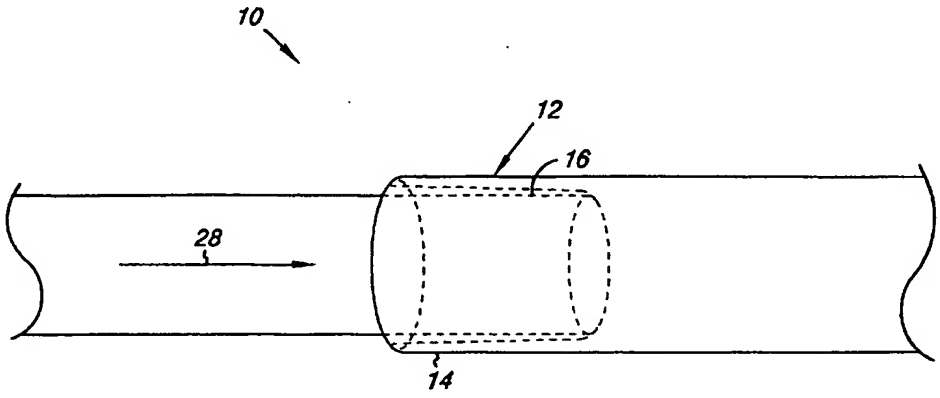
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: VENOUS VALVE APPARATUS AND METHOD



(57) Abstract: Embodiments of the invention provide for a unidirectional flow valve. For example, embodiments of the invention include a method of providing a unidirectional flow valve to a vein that include folding a first portion of a vein over an adjacent second portion of a vein and engaging at least two opposing areas of the second portion of the vein to adjacent areas of the first portion of the vein. The at least two opposing walls of the second portion of the vein define the unidirectional flow valve. At least one support device may be inserted into the forded valve region of the vein to maintain the folded configuration of the valve.

WO 2004/037128 A1

Venous Valve Apparatus and Method

This application claims priority from U.S. Provisional Application Serial No. 60/420,905, filed October 24, 2002, the entire content of which is incorporated herein by reference.

Technical Field

The present invention relates generally to apparatus, systems, and methods for use in a body lumen; and more particularly to a valve apparatus for use in the vasculature.

Background

In human pathology, the proper functioning of venous valves is important. Chronic venous diseases such as chronic venous insufficiency and varicose veins may result in incompetence of venous valves. Venous insufficiency is believed to contribute to various maladies, including chronic venous insufficiency, edema, varicose veins, aching leg pain while standing, lipodermatosclerosis, and ulcerations. Venous insufficiency is essentially caused by venous hypertension and chronic venous stasis due to valvular incompetence both of an idiopathic nature and of a secondary nature following past illnesses of the venous systems.

A replacement venous valve may regulate the direction of the pulsating blood flow so as to limit the occurrence of blood stasis in the region about the valve. By maintaining the direction of blood flow therethrough a new venous valve may alleviate the maladies resulting from valve disorders or venous insufficiency. A replacement valve should therefore permit blood flow in the proper predetermined direction to limit or prevent backflow of the blood in a reverse direction.

BRIEF DESCRIPTION OF DRAWINGS

A detailed description of the invention is hereafter described with specific reference being made to the drawings.

Figure 1 is a perspective view of an embodiment of the invention wherein a portion of a vein is configured to act as a valve.

Figure 2 is a cross-sectional view of the embodiment shown in Figure 1 wherein the configured vein is shown during prograde blood flow.

Figure 3 is a cross-sectional view of the embodiment shown in Figure 1 wherein the configured vein is shown during retrograde blood flow.

Figure 4 is a perspective view of an embodiment of the invention including a saddle for establishing and supporting a region of a vein configured to act as a valve.

Figure 5 is a perspective view of an embodiment of the invention including a saddle for establishing and supporting a region of a vein configured to act as a valve.

Figure 6 is a perspective view of the portion of a vein configuration shown in Figure 1 with the ring support of Figure 4 positioned therein.

Figure 7 is a side view of a vein having an embodiment of the invention including a catheter assembly for use in configuring a region of the vein to act as a valve positioned therein.

Figure 8 is a side view of the vein containing the embodiment of the invention depicted in Figure 7 shown during balloon deployment.

Figure 9 is a side view of the vein containing the embodiment of the invention depicted in Figure 8 shown during evacuation of a region of the vein between the deployed balloons to collapse the region.

Figure 10 is a side view of the vein containing the embodiment of the invention depicted in Figure 9 shown during balloon collapse.

Figure 11 is a side view of the vein containing the embodiment of the invention depicted in Figure 10 wherein the saddle is engaged to a portion of the collapsed region of the vein.

Figure 12 is a side view of the vein containing the embodiment of the invention wherein the saddle and a portion of the collapsed region of the vein engaged thereto are moved into an adjacent portion of the vein to provide the vein with a valve configuration.

Figure 13 is side view of the vein shown in Figures 7-13 wherein the catheter has been removed from the valve configured region of the vein.

Figure 14 is a perspective view of an embodiment of the invention wherein the valve region comprises a single valve wall or leaflet.

Figure 15 is a perspective view of the embodiment shown in Figure 14, with the valve wall or leaflet in the closed configuration.

Figure 16 is a perspective view of an embodiment of the invention wherein the valve region comprises a single valve wall or leaflet.

DETAILED DESCRIPTION

Embodiments of the present invention may include different forms. The description herein provides an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated. For the purposes of this disclosure, like reference numerals in the figures shall refer to like features unless otherwise indicated.

The present invention is directed to several embodiments. For example, in at least one embodiment the invention is directed to an apparatus for forming a valve in a vein utilizing the vein itself to form the valve. In some embodiments the apparatus includes a support and/or a fixation device that may be used to form the valve intravenously, extravenously or in a combination of intravenous, and extravenous locations.

In some embodiments the apparatus includes, but is not limited to, one or more ring-like support members or saddles, which retain portions of the vein wall in a position to form a functional valve. In some embodiments the apparatus further includes, but is not limited to, a stent or other implantable and expandable medical device to provide a fold region within the vein through which portions of the vein and support member are positioned to form the valve.

In at least one embodiment the invention is directed to a method of forming a valve utilizing the vein itself. In some embodiments the invention is directed to a method for dissecting the vein from surrounding tissue, thereby freeing the vein to allow longitudinal and axial movement and repositioning of a portion of the vein to form the valve. In some embodiments portions of the reconfigured vein may be tacked together to maintain the valve structure. In some embodiments an expandable member such as a stent is deployed within the vein to provide a point about which an adjacent portion of the vein is folded to provide the valve configuration. In some embodiments one or more saddle members are placed in the reconfigured region of the vein to support the vein and maintain the valve configuration.

In at least one embodiment the invention is directed to a method for forming a valve using entirely percutaneous access methods, or by minimally invasive access methods, or a combination thereof. In some embodiments the invention is directed to a catheter assembly and its methods of use for preparing and/or forming a valve region of a vein by collapsing a region of the vein and/or folding the walls of the vein to provide the vein with a valve configuration. In some embodiments the catheter assembly is

provided with one or more balloons to define a valve region and/or deploy a stent and/or a saddle in order to establish and/or maintain the valve configuration of the vein.

Turning to Figure 1 a first embodiment of the invention is depicted which includes a portion of a vein, indicated generally at reference numeral 10, which is folded over itself to provide the vein with a valve region 12. The valve region 12 acts as a unidirectional blood flow valve in the manner of an existing venous valve. Valve region 12 is provided to the vein 10 by folding a first or outer portion 14 of the vein over a second or inner portion 16 of the vein and retaining the folded configuration by engaging one or more portions of the first portion 14 to adjacent portions of the second portion 16. In at least one embodiment the folding is accomplished endoluminally using a catheter rather than using an external surgical approach.

There are several techniques and devices that may be utilized to form the valve region 12 within the vein as well as to maintain the folded configuration of the valve thereafter. For example, in the embodiment shown in Figure 1, the vein may be endoluminally or surgically manipulated and folded in the manner shown and described herein. To retain the folded configuration of the valve region 12, the outer portion 14 of the folded vein is engaged to the inner portion 16 of the vein at a plurality of points, such as are indicated by reference numerals 18 and 20 in Figures 2 and 3.

In some embodiments valve region 12 may be formed using a vein segment or other autologous or non-autologous biological material and implanted into the desired location to provide valve region 12 in vein 10.

Engagement of selected points of the inner portion 16 and outer portion 14 of the vein has the effect of defining a valve opening 22 with the opposing walls 24 and 26 of the inner portion 16. Depending on the tautness of the region of the vein used to define the opening 22, the opening may also be characterized as a slit. When blood is flowing through the opening or slit 22 in a normal prograde direction, such as when the blood is under positive pressure, as indicated by arrow 28 in Figure 1, the walls 24 and 26 of the inner portion 16 are pushed outward, as indicated by arrows 30 in Figure 2, to allow free flow of blood through the opening 22. However, if for whatever reason, the flow of blood through the vein is reversed or becomes retrograde, i.e., under negative pressure, the pressure exerted on the opening 22 will cause the walls 24 and 26 to collapse inward, as indicated by arrows 32 in Figure 3, thus closing the opening 22 and preventing the retrograde flow.

Vein portions 14 and 16 may be engaged together to maintain the valve region

12 in a variety of different and/or complimentary manners. For example, in the embodiment shown in Figures 2 and 3 the portions may be sutured, tacked, thermally bonded, glued, and/or otherwise secured together at junctions 18 and 20 or at other areas as may be desired to maintain the valve region 12 and provide the unidirectional opening 22.

In some embodiments a biasing member or support device may be inserted within the vein to maintain the folded configuration of the valve region 12 by pushing selected portions of the inner portion 16 against the outer portion 14 to form opening 22. Some examples of such a support device are shown in Figures 4 and 5, wherein a valve maintaining support includes, but is not limited to, a substantially ring-like member or saddle 40, which may inserted into the vein to maintain the folded configuration of the valve region 12 by biasing portions of the inner portion 16 of the vein 10 against corresponding portions of the outer portion 14 of the vein10 such as in the manner shown in Figure 6.

As shown in Figures 4 and 5, the saddle 40 may be constructed of one or more wires or bands 42 of material. The saddle may be constructed from one or more metals and/or polymer materials, including shape memory metals such as nitinol, and/or shape memory polymers, and/or bioabsorbable materials. In one embodiment, the material of the saddle can be biocompatible or is coated with one or more biocompatible coatings.

The saddle 40 defines at least two biasing regions 44 and 46 that as a result of inherent biasing tension and/or as a result of transitioning from a reduced state to an expanded shape memory state, push the inner portion 16 of the vein 10 against the outer portion 14 of the vein 10 at junctions 18 and 20 as shown in Figure 6. As a result, the saddle 40 maintains the folded configuration of the valve region 12 of the vein 10 without the need to surgically or externally affect the vein 10 such as by bonding the vein portions together as previously described, although such procedures may be utilized in conjunction with the saddle 40 if desired.

Some embodiments of the invention may include one or more support devices. For those embodiments having two or more support devices, both devices may be positioned inside the vein, both may be positioned outside the vein, and/or one may be inside and the other outside. Other configurations for the one or more support devices are also possible. Support devices may include one or more saddle-shaped rings, one or more stents or similar structures, and/or a combination of the two. Other types of supports may include an anchor bar extending between opposite sides of the vessel,

circular or helical rings, tacks, barbs and interlocking components.

As indicated above, the present invention provides for a variety of methods for forming the folded configuration of the valve region 12, a variety of methods for preparing a selected region of the vein for folding, and a variety of methods for maintaining the valve region 12 in its folded configuration. Additionally, the present invention provides for embodiments directed to catheters and catheter systems for carrying out one or more of the various methods described.

An example of such an inventive catheter assembly, indicated generally at 100, is depicted in Figures 7-13. In Figures 7-13 the catheter 100 is shown carrying out the steps of at least one of the inventive methods for preparing the vein 10 for folding and folding a portion of the vein 10 to form the valve region and deploying a saddle 40 therein.

As is shown in Figure 7, prior to formation of the valve region the catheter 100 includes, but is not limited to, a catheter shaft 112 having at least two expandable members or balloons 114 and 116 positioned thereon. It should be recognized that it is inherent that the catheter shaft 112 defines an inflation lumen or other mechanism (not shown) for expanding the balloons 114 and 116.

Also disposed about the shaft 112 is a support device or saddle 40 in a reduced low profile configuration. The saddle 40 may be held in the reduced state by any of a variety of known retaining devices such as one or more retractable sleeves, sheathes, socks, and bioabsorbable retaining bands, which when removed from the saddle 40, the saddle is allowed to expand to its nominal or expanded state such as is shown in Figures 11-13. In embodiments where the saddle 40 is at least partially constructed of a shape memory material, the saddle may be retained in the reduced profile configuration shown in Figure 7 until the material is triggered to achieve one or more expanded states such as are shown in Figures 11-13.

In some embodiments of the invention the catheter 100 may also be equipped with one or more stents or other expandable endoprosthetic support devices. In the embodiment shown in Figure 7 the support device can be a stent 120, such as a balloon expandable stent positioned about the first balloon 114. In some embodiments support device may be self-expandable or hybrid expandable as desired and may be positioned anywhere along the catheter shaft 112 prior to delivery.

In practice the catheter 100 is advanced through the vein 10 to a selected region 118 of the vein 10 where it is desired to form a valve region. The catheter 100 is

positioned such that the balloons 114 and 116 are adjacent to the ends of the selected region 118. Once the catheter 100 is positioned in this manner, the balloons 114 and 116 are expanded such as is shown in Figure 8 to isolate the region of the vein 10 which is to be prepared for valve formation.

To facilitate folding the vein 10, it is desirable to collapse the vein 10 in order to facilitate engagement of the vein wall 13 to the biasing regions 44 and 46 of the saddle 40. In some embodiments of the invention the shaft 112 defines a vacuum or evacuation port 130 and an evacuation lumen 132 through which the blood present in the selected region 118 may be evacuated in order to collapse the selected region 118 of the vein 10 as is shown in Figure 9. In some embodiments of the invention the catheter 100 includes an injection device 134 which is advanced through the shaft 112 and passed outward through the vein wall 13 to deploy inject material 136 about the selected region 118 of the vein 10. The inject material 136 may be any material such as including but not limited to: saline, contrast medium, anesthetic solution, air, carbon dioxide, or any suitable liquid, gas or combination thereof. The inject material 136 will aid in separating the vein 10 from the surrounding extra-vascular tissue and thereby aid in collapsing the isolated selected region 118 with out the need to surgically expose the vein 10.

In some embodiments a device such as a helical wire or other device may be passed around the vein 10 to limit any expansion of the vein 10 which may occur, for example, by internal device expansion such as support device, or by dilatation due to internal pressure. The helical wire or other device can be introduced from within the vein and passed through an opening created in the vein wall, or can be placed surgically.

Once the selected region 118 of the vein 10 is collapsed, such as is shown in Figure 10, the balloons 114 and 116 are collapsed and the stent 120 is deployed adjacent to the collapsed selected region 118 of the vein.

The deployed stent 120 acts to support and define the outer portion 14 of the vein 10. Once the stent 120 is deployed the biasing regions 44 and 46 are freed to expand radially outward from the catheter shaft 112 to engage the wall 13 of the selected region 118 of the vein 10, such as is shown in Figure 11. When the biasing regions 44 and 46 of the saddle 40 are initially freed to expand the opposing end(s) 45 of the saddle 40 remain in the reduced configuration engaged to the catheter shaft 112.

As is shown in Figure 12, following the partial deployment of the saddle 40 and engagement of the vein wall 13 by the biasing regions 44 and 46, the catheter 100 is

drawn back through the deployed stent 120. Drawing the catheter 100 through the stent 120 pulls the saddle 40 as well as the portion of the vein engaged thereto through the stent 120 as well. Because the stent 120 is fixed in place within the vein 10, the vein wall 13 is forced to fold at fold point 121 about the edge of the stent 120. Thus, the portion of the vein disposed about the stent becomes the outer portion 14 of the valve region 12 and the portion of the vein 10 drawn through the stent 120 becomes the inner portion 16.

After the valve region 12 is formed in the manner described above, the ends 45 of the saddle 40 are released from the shaft 112 (shown in Figure 12) and the saddle is allowed to fully deploy within the vein 10 and the catheter may be withdrawn as shown in Figure 13. The saddle 40 retains the folded configuration of the valve region 12 in the manner previously described to provide the vein 10 with a unidirectional valve such as is shown in Figures 2 and 3.

Although the embodiments depicted in Figures 1-13 incorporate valve configurations with two valve leaflet surfaces, the present invention can also be directed to embodiments having one or more leaflets or walls 24/26 such as are depicted in Figures 14-16. So, valve configurations can include one, two, or three leaflets analogous to opposing walls 24 and 26 shown in Figures 2 and 3.

In Figures 14-15 a valve region 12 is provided with a single leaflet or wall 24/26. Figure 14 shows the vein with the leaflet 24/26 in the open configuration and Figures 15 shows the leaflet 24/26 in the closed configuration.

In the embodiment shown in Figure 16, a valve region 12 is shown having three leaflets or walls 24/26.

The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims.

Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should

be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g. each claim depending directly from claim 1 should be alternatively taken as depending from all previous claims). In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

This completes the description of the embodiments of the present invention. Those skilled in the art may recognize other equivalents to the specific embodiment described herein which equivalents are intended to be encompassed by the claims attached hereto.

We claim:

1. A method of providing a unidirectional flow valve comprising:

folding a first portion of a vein over an adjacent second portion of the vein; and

engaging at least two opposing areas of the second portion of the vein to adjacent areas of the first portion of the vein with at least one support device, wherein at least two opposing walls of the second portion of the vein define the unidirectional flow valve.

2. The method of claim 1, wherein folding the first portion of the vein includes:

isolating the second portion of the vein;

collapsing the second portion of the vein;

inserting a first support device into the first portion of the vein adjacent to the second portion of the vein, the first support device including a substantially hollow tubular member with a flow path therethrough;

inserting a second support device in a partially expanded state in the collapsed second portion of the vein, at least two portions of the second support device engaging the at least two opposing areas of the second portion of the vein;

folding the first portion of the vein over the second portion of the vein by advancing the second support device in the partially expanded state and by association the at least two opposing areas of the second portion of the vein through the flow path of the first support device; and

expanding the second support device to a fully expanded state, where in the fully expanded state the at least two portions of the second support device bias the at least two opposing areas of the second portion of the vein against the adjacent areas of the first portion of the vein.

3. The method of claim 2, wherein the first support device includes a stent.

4. The method of claim 3, wherein the first support device is at least partially constructed from at least one shape memory material.

5. The method of claim 3, wherein the first support device is balloon expandable.

6. The method of claim 2, wherein the second support device includes a saddle.

7. The method of claim 6, wherein the saddle includes at least one substantially ring-like member having a reduced configuration, a partially expanded configuration and a fully expanded configuration.

8. The method of claim 2, wherein isolating the second portion of the vein includes:

advancing a catheter through the vein to a position under the second portion of the vein, the catheter including a catheter shaft, a first balloon, and a second balloon, the first balloon being positioned adjacent to a first end of the second portion of the vein and the second balloon being positioned adjacent to second end of the second portion of the vein; and

inflating the first balloon and the second balloon.

9. The method of claim 8 wherein the catheter shaft defines an evacuation port and an evacuation lumen, and wherein collapsing the second portion of the vein includes evacuating the second portion of the vein after isolating the second portion of the vein by expanding the first balloon and the second balloon.

10. The method of claim 2, wherein collapsing the second portion of the vein includes:

separating at least the second portion of the vein from surrounding tissue; and

evacuating the isolated second portion of the vein.

11. The method of claim 10, further including inserting a third support device through the vein and around at least the second portion of the vein.

12. An apparatus comprising:

at least one support device defining a first biasing surface and a second biasing surface, the first biasing surface constructed and arranged to engage a first area of an inner portion of a folded region of a vein against an adjacent area of an outer portion of the folded region of the vein, the second biasing surface constructed and arranged to engage a second area of the inner portion of the folded region of the vein against an

adjacent area of the outer portion of the folded region of the vein for maintaining the folded region of the vein in a folded configuration in order to allow the inner portion of the folded region to act as a unidirectional valve.

13. The apparatus of claim 12, wherein the at least one support device includes at least one substantially ring like member.

14. The apparatus of claim 12 wherein the at least one support device further includes a stent, wherein the stent provides the folded region of the vein.

15. The apparatus of claim 14, wherein the stent provides support for the outer portion of the folded region of the vein.

16. The apparatus of claim 14, wherein the at least one support device further includes a helical member adapted to be passed around the vein to limit expansion of the vein.

17. A catheter for use in forming a unidirectional valve in a vein, the catheter comprising:

a catheter shaft;

at least two expandable balloons positioned on the catheter shaft;

an expandable support member, the expandable support member being disposed about one of the balloons in a reduced state, the expandable support member being expandable from the reduced state to an expanded state; and

an expandable saddle member, the expandable saddle member including a first biasing region, a second biasing region and at least one end region, the expandable saddle member having a reduced state, a partially expanded state and a fully expanded state.

18. The catheter of claim 17, wherein in the reduced state for the expandable saddle member the first biasing region, the second biasing region and at least one end region are engaged to the catheter shaft, in the partially expanded state the first biasing region and the second biasing region are free to expand radially outward from the catheter shaft but the at least one end region remains engaged to the catheter shaft, and in the fully

expanded state the first biasing region, the second biasing region and the at least one end region are all free to expand radially outward from the catheter shaft.

19. The catheter of claim 17, wherein the catheter shaft defines an evacuation port and an evacuation lumen in fluid communication therewith, the evacuation port being positioned between the at least two expandable balloons.

20. The catheter of claim 17, wherein the catheter further includes an injection device extending along the catheter shaft and is constructed and arranged to be advance through a vein wall to deposit injection material about a selected portion of the vein.

21. The catheter of claim 17, wherein the injection material is selected from at least one member of the group consisting of: saline, contrast medium, anesthetic solution, air, carbon dioxide, and any combination thereof.

22. The catheter of claim 17, wherein the expanded support member includes a stent.

23. The catheter of claim 17, further including a helical member disposed within a lumen of the catheter shaft, wherein the helical member deploys from the lumen and limits the expansion of the expandable support member.

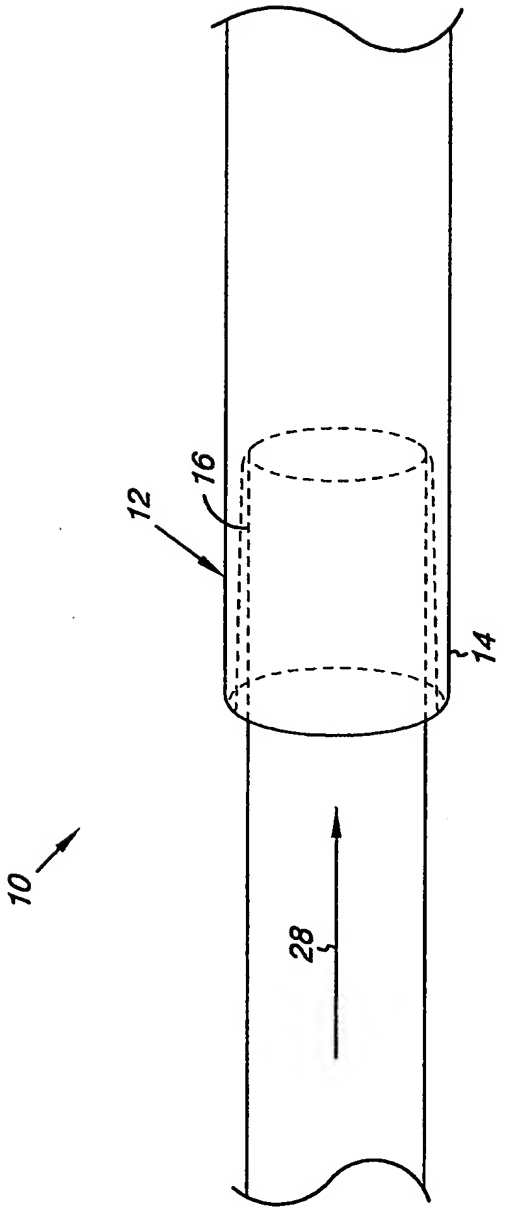


Fig. 1

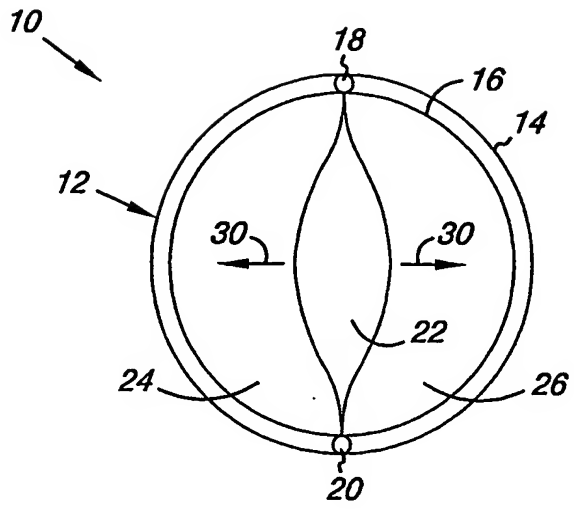


Fig. 2

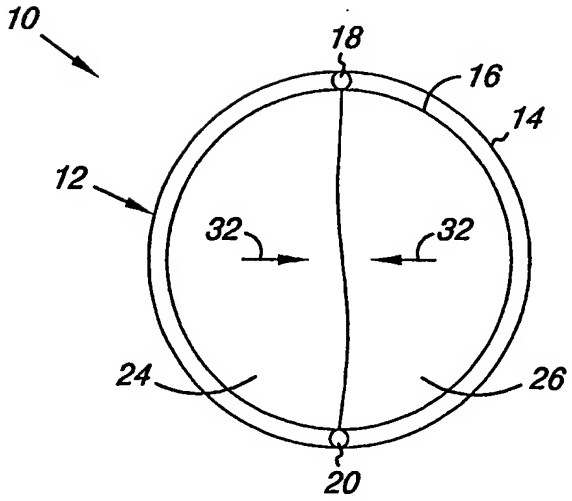


Fig. 3

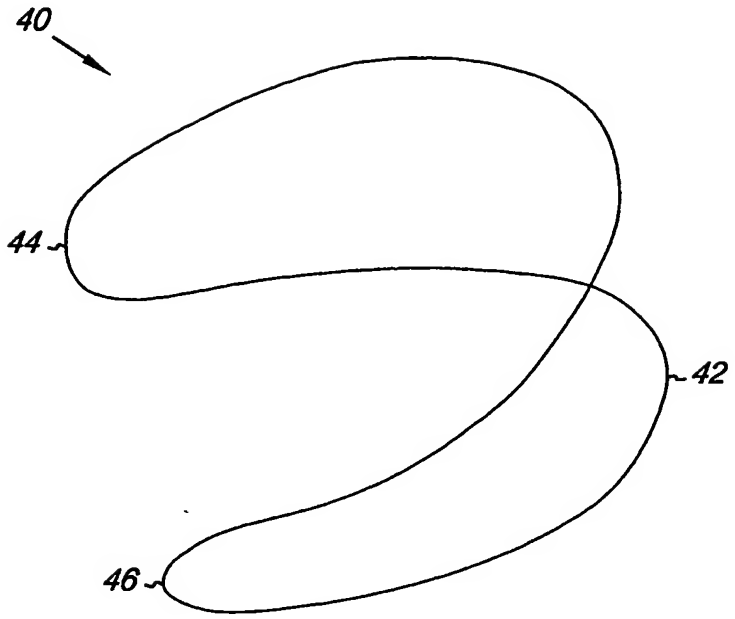


Fig. 4

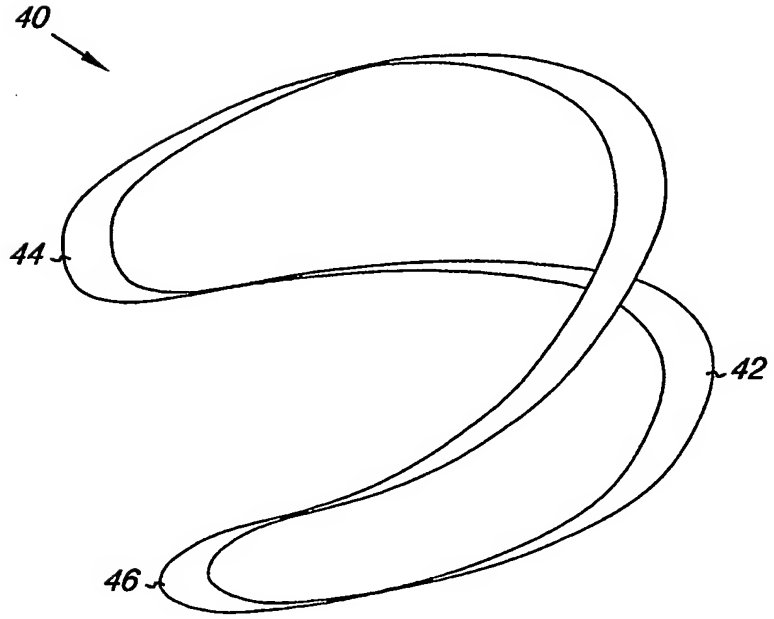


Fig. 5

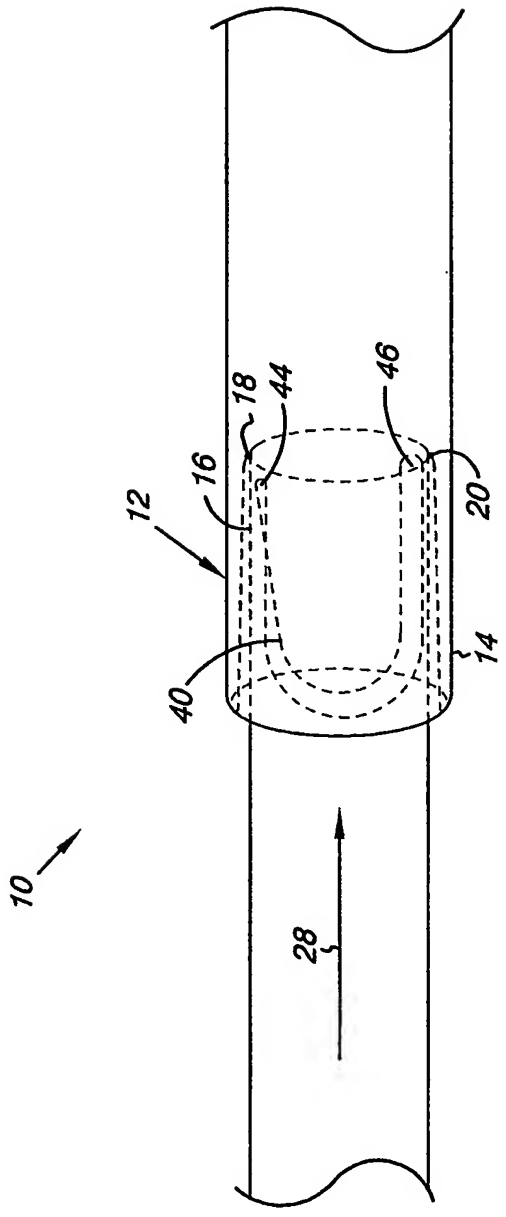


Fig. 6

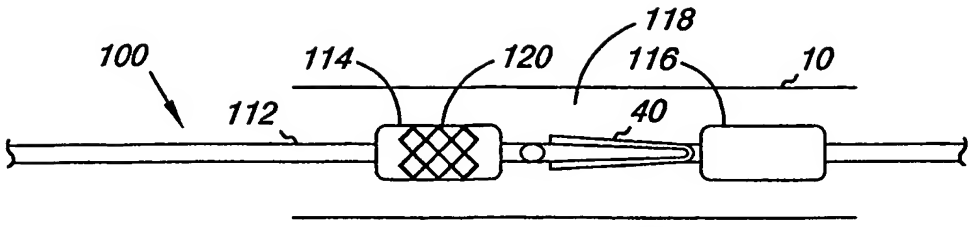


Fig. 7

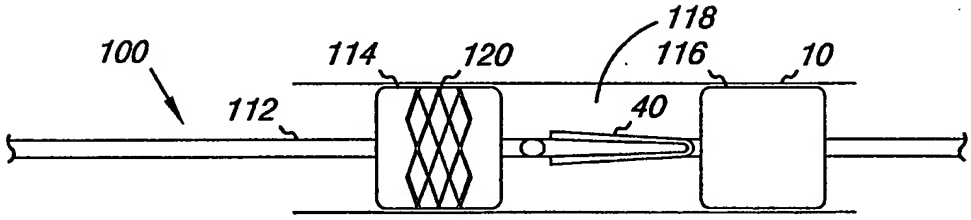


Fig. 8

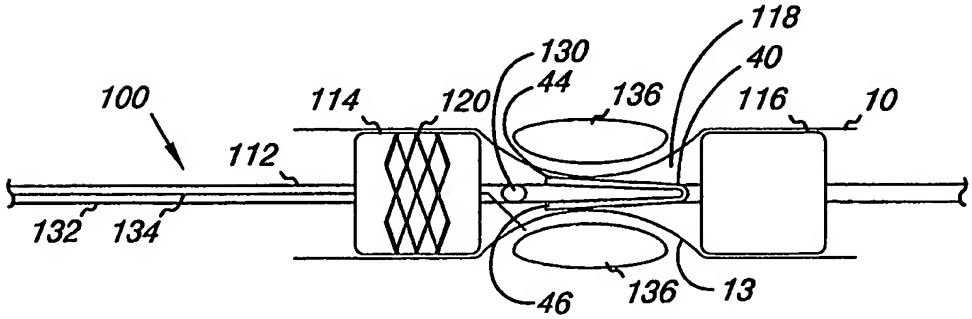


Fig. 9

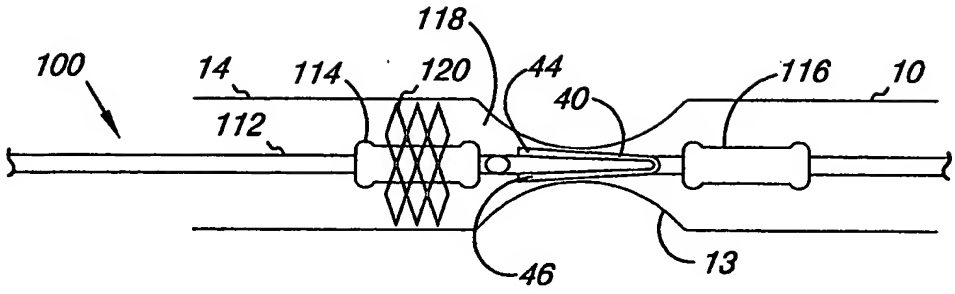
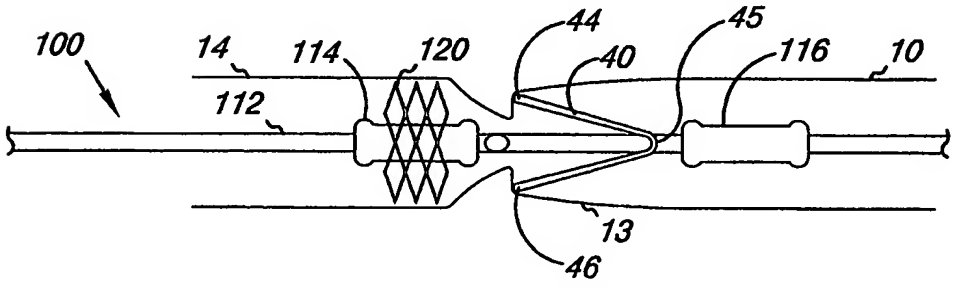

118
100
14
114
120
44
40
116
10
112
46
13

Fig. 10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45
100
14
114
120
40
116
10
112
13
46

Fig. 11

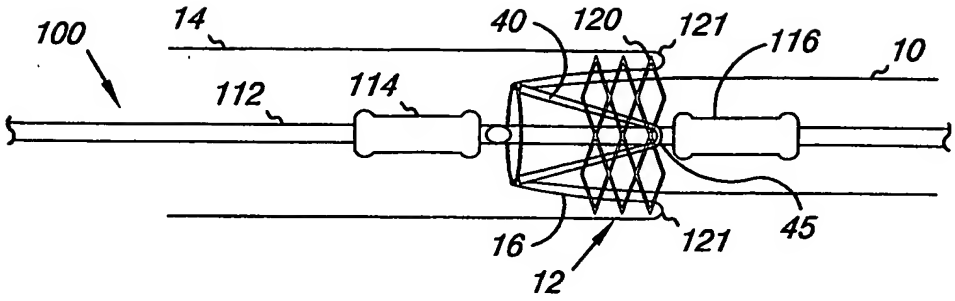
100
14
40
120
121
116
10
112
114
45
16
121
12

Fig. 12

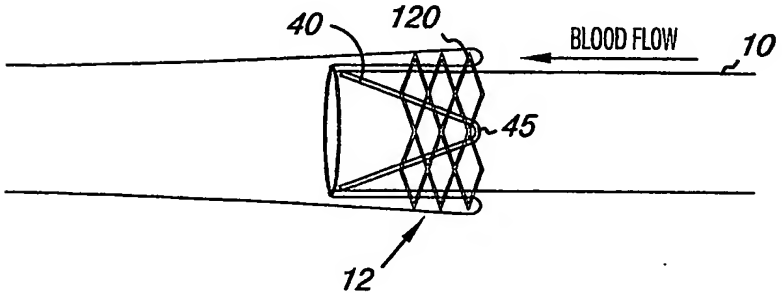
40
120
BLOOD FLOW
10
45
12

Fig. 13

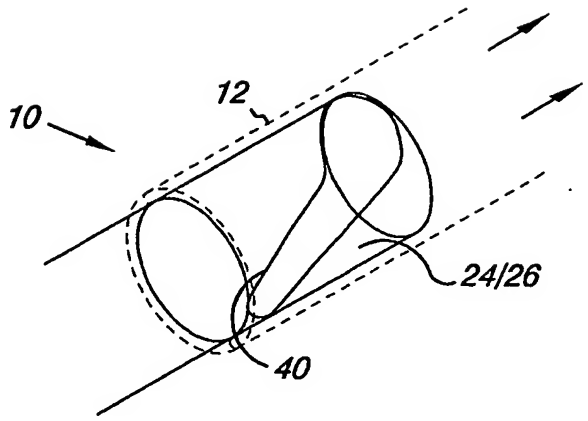

Fig. 14

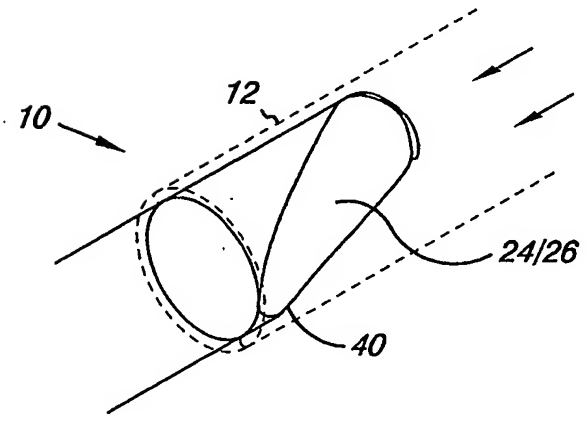

Fig. 15

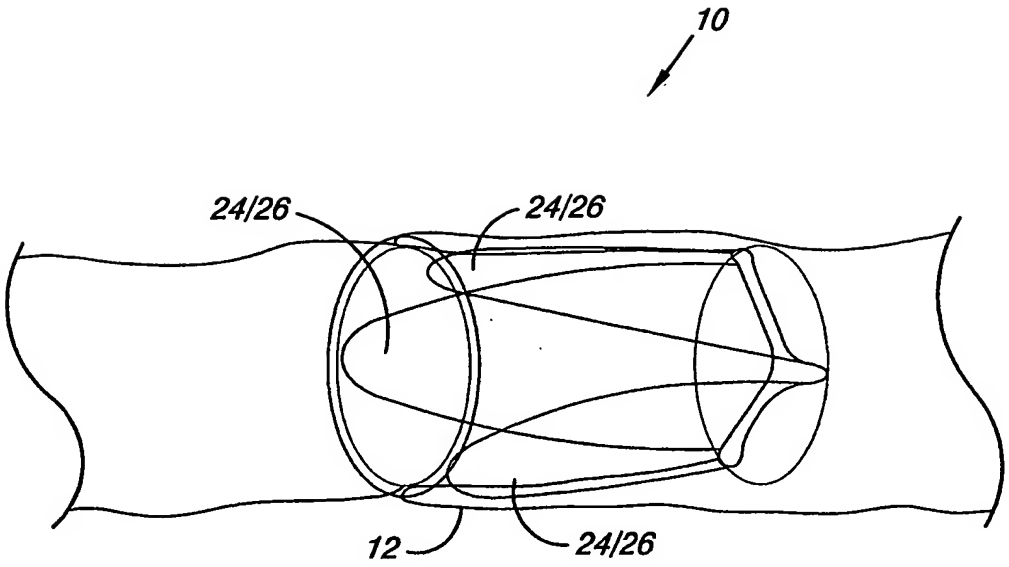

Fig. 16

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/33521

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
WPI Data, EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/039450 A1 (PAVCNIK ET AL) 8 November 2001 (2001-11-08) figures 4,43	12,13
A	WO 02 26168 A (TRICARDIA, LLC) 4 April 2002 (2002-04-04) abstract; figures	17
A	WO 88 00459 A (QUOTIDIAN NO. 100 PTY. LIMITED) 28 January 1988 (1988-01-28)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 March 2004	24/03/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/33521

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-11
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internatio plication No
PCT/US 03/33521

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		CA 2397746 A1	09-08-2001
		EP 1251805 A2	30-10-2002
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